

Sub 23

12(New). -A recombinant adeno-associated virus comprising sequences encoding factor IX and regulatory control sequences which permit expression of factor IX in a cell, wherein the level of contaminating adenoviral helper virus is no greater than that obtained by subjecting said recombinant AAV to four rounds of cesium chloride gradient centrifugation.

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13(New). A composition comprising a physiologically compatible carrier and a recombinant adeno-associated virus comprising sequences encoding factor IX and regulatory control sequences which permit expression of factor IX in a cell, wherein the level of contaminating adenoviral helper virus is no greater than that obtained by subjecting said recombinant AAV to four rounds of cesium chloride gradient centrifugation.

14 (New). The composition according to claim 13, wherein said composition comprises about 1×10^8 to about 5×10^{11} particles of the recombinant adeno-associated virus.

15(New). The composition according to claim 14, wherein said composition comprises at least 10^9 particles of the recombinant adeno-associated virus.

16 (New). The composition according to claim 13, wherein the composition comprises 10^{12} to 10^{13} genomes of the recombinant adeno-associated virus per milliliter carrier.

17 (New). The composition according to claim 13, wherein said composition is formulated for intramuscular injection.